

The Epidemiology of Burkitt Lymphoma in East-African Children and Minors (EMBLEM)

Study Status Update, Staff Meeting, and Cancer Research Methods Workshop

September 17-20, 2012

Mwanza Interventions Trials Unit
Tanzanian National Medical Institute for Research
Isamilo Road,
Mwanza, Tanzania











Meeting/Workshop Purpose

The Cancer Research Methods Workshop was an opportunity for the entire team to meet in person for the first time, provide status updates, and to share success stories and challenges. This included the clinical, administrative, and support staff from the six EMBLEM sites in Kenya, Tanzania, and Uganda; the project sponsor from the National Cancer Institute (NCI), and staff from Westat, NCI's support services contractor. The Workshop for EMBLEM project staff was planned to coincide with the "Infectious & Cancer" scientific sessions in Mwanza, Tanzania (which was sponsored in part by research organizations in Italy, namely the Istituto Oncologico Romagnolo, the Associazione Vittorio Tison and the Istituto Scientific Romangol per lo Studi e la Cura Dei Tumori) held at the Gold Crest Hotel from September 17-18, 2012. The Workshop was also an opportunity to provide training to the EMBLEM project team and a number of invited observers with interests in oncology research. The workshop was a team building opportunity for staff from all sites to share project experiences and learn more about the processes of study management, study monitoring and quality management, and cancer research methods. The meeting also served to strengthen relationships among the study investigators and other stakeholders within the region by highlighting the work of EMBLEM, an added benefit that, it is hoped, will bolster visibility and, thus, recruitment efforts overall.

<u>Venue</u>

The meeting was held in the conference facilities of the Mwanza Intervention Trials Unit (MITU) on the campus of the National Medical Institute for Research (NMIR) in Mwanza, Tanzania. The venue included two large conference rooms allowing for the presentation of simultaneous meeting discussion tracks. The larger of the two conference rooms was staffed by a sound technician. In addition, the EMBLEM Tanzania team arranged for meals and coffee/tea breaks to be served on the grounds of MITU, providing opportunities for team interaction and impromptu discussions. The Tanzanian team also facilitated the timely end of break periods so that workshop presentations could proceed as scheduled.

Attendance

A total of 55 persons attended the EMBLEM staff meeting, including staff persons from each of the six study sites in Uganda, Tanzania and Kenya, and invited speakers and guests. The audience for the workshop was varied, and consisted of nurses, research assistants, physicians, laboratory scientists, drivers, university professors, office managers and other administrative staff, site

monitors, ethicists, project managers, pathology specialists, medical superintendents, data managers, and study coordinators. (See the list of attendees in Appendix 1.) In addition, the workshop organizers arranged to have special guest Nyamagana Tanzania Member of Parliament Hon. Hezekia Wenje address the group during the opening session on September 17th. At the end of the presentation, each meeting attendee received a certificate of attendance for the EMLBEM project meeting.

Session Overviews

The meeting included an opening session followed by presentations addressing topics in Study Status, Research Project Management, and Cancer Research Methods. (See the meeting agenda in Attachment 2).

Opening Session – Monday, September 17: Dr. Esther Kawira, EMBLEM Tanzania Principal Investigator (PI) and Captain Josiah Magatti, EMBLEM Tanzania Study Coordinator, extended warm welcomes to all attendees and thanked the committee in Tanzania for their work to organize the meeting. This included mention of the participation in logistical arrangements by the EMBLEM Tanzania Co-Investigator Dr. Nestory Masalu, who was unfortunately not able to attend the project meeting due to a death in his family.

Dr. Kawira also introduced the EMBLEM teams from each country, including Dr. Martin Ogwang, EMBLEM Uganda Principal Investigator from St. Mary's Lacor Hospital in Gulu, Uganda. Dr. Ogwang delivered an overview of the EMBLEM study accomplishments to date and expressed his hope that the EMBLEM study would also serve as an example of scientific cooperation among East African countries.

Dr. Ogwang introduced Hon. Hezekia Wenje, Member of Parliament from Nyamagana District in Tanazania, who addressed the group with impassioned praise for the work undertaken by the EMBLEM team, noting his strong support of the project. Hon. Wenje also expressed his hope that the EMBLEM study, with its scientific goals and added benefit to the health of East African children, could serve a greater goal of helping to unite the people of East Africa. (Media personnel from Star TV covered the event, and later interviewed MP Hon. Wenje and Dr. Ogwang.) Dr. Peter Odada from EMBLEM Kenya also expressed his hope that the EMBLEM study would serve as a springboard to cooperative research in other cancers.

Dr. Tobias Kinyera, Study Coordinator for EMBLEM Uganda, provided a description of Burkitt Lymphoma (BL), an aggressive B-cell lymphoma. He also explained the study design challenges that had been met in Uganda by developing a strategy for

identifying three types of controls to account for potential biases in underlying malaria exposure (controls matched to cases, population-based controls, and health center controls). Dr. Kinyera's presentation was informative, insightful, and was delivered with both humor and compassion.

Status Updates

Dr. Esther Kawira presented a brief history of Burkitt Lymphoma in Tanzania, including some early photographs (believed to be the first photographs taken) of Tanzanian children who are thought to have had BL. She pointed out the successful treatment of BL with standardized chemotherapy. Community sensitization posters used in Tanzania (both in English and Swahili) were on display in the conference room.

Dr. Constance Tenge, EMBLEM Kenya Principal Investigator, provided a summary of start-up activities in Kenya, including the assembling of a multi-disciplinary team. She described the challenges and resolutions identified by the EMBLEM team. This included the management of multi-source funds to cover various aspects of the study, becoming proficient at study flow from enrollment through data and specimen processing, and the interaction with government agencies to seek tax exempt status for the equipment necessary to implement the study.

Dr. Martin Ogwang discussed challenges encountered and resolved in order to successfully initiate the study in Uganda. These challenges included working within the framework of hospitals established primarily to provide care rather than to enable scientific research, with further required training in Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP) guidelines and compliance, and ethical human subjects considerations. Dr. Ogwang attested that meeting these challenges, in addition to the infrastructure challenges of inconsistent power and internet provision, has required and will continue to necessitate a spirit of cooperation rather than competition.

Research Project Management – September 18th – **19**th: Detra Robinson, a Westat senior manager with international training experience prepared and delivered presentations and facilitated discussions on the principles of research project management. These sessions were attended by both administrative and scientific field staff in addition to other stakeholders. Ms. Robinson's discussions focused on the fundamentals of communication and appropriate documentation of project processes. She delivered presentations on the management of cost, quality, risk, time, and human resources – and drew some examples from research

projects. She suggested using these fundamental principles as goals for study management rather than requirements. Janet Lawler-Heavner facilitated a discussion of field management strategies that provided the EMBLEM study coordinators and team members an opportunity to discuss how the sites had overcome study implementation challenges, particularly with regard to identifying potential research participants. During this session, Study PI Dr. Sam Mbulaiteye added comments and answered questions. All research project management sessions stimulated considerable positive interaction from the participants, who related the concepts to both EMBLEM and potential future project environments.

Ethics and the EMBLEM Study Consent – September 19th: Professor Robert Wachbroit, a University of Maryland Ethicist, had the opportunity to observe field activities at the study sites at Lacor Hospital, and in Kuluva, Uganda during the weeks leading up to the meeting. His presentation to the workshop audience focused on some of the more controversial aspects of the consent process, specifically as they relate to EMBLEM, including consent/assent of minors, prospective and total withdrawal from study participation, the ethical challenges of incidental findings, the obligation of providing ancillary care, and returning individual research results, particularly as they relate to potential genetic testing.

Cancer Research Methods - September 18th - 20th: Professor Mayur Desai, a senior epidemiologist and educator from Yale University, presented sessions on epidemiologic study design and sampling methodology, measurement validity and reliability, measures of exposure association, and methods for dealing with bias, confounding and exposure interaction. These sessions were well-received and provided both background and supplemental information to EMBLEM staff and other stakeholders. As part of this track, Professor Henry Wabinga from the Uganda Cancer Registry provided an overview of the role of cancer registration in the measurement of disease burden.

Study Monitoring – September 20th: Professor Moses Joloba and Mr. Samuel Kirimunda, experienced EMBLEM study monitors from Makerere University in Kampala, Uganda, presented the methods used for performing site monitoring visits for the EMBLEM study, and led discussions of study monitoring, covering topics such as an overview of the purpose and role of the study monitor, the EMBLEM consent process, sample management and specimen query resolution, data quality management, EMBLEM site-specific challenges, communicating findings during on-site monitoring visits, and preventive and corrective actions. Their presentations highlighted the importance of the supportive role of the study monitor during the monitoring process, particularly since feedback to the site staff is often perceived as adversarial. They also reinforced a number of quality management principles discussed during the Research Project Management sessions. The corrective action review discussion, in particular, was helpful in describing monitoring

issues common across all sites with the intent of improving study operations overall. In addition, the study monitors conducted the annual site visit at the Bugando EMBLEM office and laboratory during the course of the week.

Workshop Accomplishments and Next Steps

Throughout the workshop, all study staff, invited speakers and other project stakeholders had the opportunity to share both EMBLEM and other research/work experiences while on the premises of NMIR. The attendees also took advantage of the meal and coffee/tea breaks each day to engage in friendly conversations under tents on the campus grounds, thus accomplishing strong teambuilding - another of the primary objectives of the meeting.

During the wrap-up session, EMBLEM PI Dr. Sam Mbulaiteye from the National Cancer Institute addressed the attendees, congratulating everyone on a successful meeting. He summarized the accomplishments to date, and encouraged the team to continue working hard. He commented that with the growth of both the size and scientific experience of the EMBLEM staff, the next level of development should encourage the East African team to take an active role in both crafting the future research agenda and developing opportunities for translation and capacity-building for the EMBLEM team, EMBLEM stakeholders, and the wider East African community. Dr. Mbulaiteye, Dr. Kawira, and Dr. Ogwang presented each participant with a Certificate of Attendance.

The meeting was closed by Dr. John Changalucha, NIMR Director, who expressed his pleasure that the EMBLEM team had chosen the NIMR/MITU conference facilities as its meeting venue. The NIMR center in Mwanza was established in 1979 to carry out and promote medical research in Tanzania through both research and capacity-building activities. Because of the center's extensive biospecimen processing and storage expertise, Dr. Changalucha offered NIMR assistance during the future shipment of EMBLEM biospecimens. He also pledged to carry the EMBLEM message and research interests into the greater scientific community.

Dr. Changalucha posed with the group for an official project photograph at the meeting closure. Because of the knowledge gained and exchanged, the partnerships forged, and the team strengthening accomplished during this productive week, the EMBLEM team looks forward eagerly to the next project meeting.



EMBLEM staff meeting attendees, September 20, 2012. Dr. John Changalucha, Director, NIMR (row 2-center) closed the meeting.

EMBLEM Tanzania, Kenya, Uganda, and USA Team Members, Speakers and Guests

Name	Organization	Email address
1. Dr. Esther Kawira, Principal Investigator	EMBLEM Tanzania, SHED Foundation	elkawira@gmail.com
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15. Dr. Simon Ogendo, Medical	Rorya District Hospital, Tanzania	
Superintendent		
16. Dr. Gratian Lutashi, Medical	Sumve District Hospital, Tanzania	
Superintendent		
17. Dr. Stanislaus Luhaga, Medical	Bukumbi Hospital, Tanzania	
Superintendent		
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55. Janet Lawler-Heavner	Westat, USA	janetlawler-heavner@westat.com
56. Detra Robinson	Westat, USA	detrarobinson@westat.com
57. Hon. Hezekia Wenje, Member of Parliament	Nyamagana District, Tanzania	





Cancer Research Methods Workshop

Track 0	EMBLEM: Welcome Remarks, Project Status, and Wrap-Up Sessions
Track 1	Infectious & Cancer: Scientific Sessions
Track 2	EMBLEM: Cancer Research Methods
Track 3	EMBLEM: Research Project Management
Track 4	EMBLEM: Ethics
Track 5	EMBLEM: Monitoring and Quality Management

Workshop/Meeting Locations:

- Infectious & Cancer Scientific Sessions: Gold Crest Hotel, Mwanza
- EMBLEM: Welcome and Wrap-up Sessions: NMRI, Mwanza, Room 101
- EMBLEM: Cancer Research Methods: NMRI, Mwanza, Room 101
- EMBLEM: Research Project Management: NMRI, Mwanza, Room 102
- EMBLEM: Ethics: NMRI, Mwanza, Room 101
- EMBLEM: Monitoring: NMRI, Mwanza, Room 101

Consultant Speakers:

- Track 2: Mayur Desai, Yale University
- Track 3: Detra Robinson, Janet Lawler-Heavner; Westat
- Track 4: Robert Wachbroit, University of Maryland

Monday, September 17, 2012

8:15 - 9:00	Meeting Registration and Distribution of Information Packets and Name Badges	
9:00 - 10:30	Opening and Welcome Remarks Dr. Martin Ogwang, Member of Parliament Hezekia Wenje, and Other [Invited] Distinguished Guests*	
10:30 - 11:00	Tea/Coffee Break	
11:00 13:00	"Status of the EMBLEM Study by Site/Country" by Dr. Constance Tenge, Dr. Esther Kawira, and Dr. Martin Ogwang	
13:00 - 15:00	Lunch and Announcements	
15:00 - 16:00		Welcome and Opening Ceremony (Amadori D., Amadori A., Majinge C., Changalucha J.)
16:00 - 16:30	EMBLEM Study Monitoring Visit at Bugando Moses Joloba, Samuel Kirimunda and Bugando staff to be determined	Main Lecture "Epidemiology of Tumors with Infectious Etiology"
16:30 - 17:00		Main Lecture "Pathogenetic Mechanisms of Infectious Related Tumors" Chieco Bianchi L. (IOV)
17:00 - 18:00	Welcome Cocktail (for Invited Guests to the Infection & Cancer Meeting	

• Invited Distinguished Guests:

Regional Medical Officer Valentino Bangi Medical Superintendent Bunda-Lilian Ikangila Medical Superintendent Rorya-Simon Ogendo Medical Superintendent Bukumbi-Deous Malulu

Tuesday, September 18, 2012

Tuesday, Septembe	1 10, 2012		
9:00 - 10:00	Pre-Test Introduction to Epidemiology: Measures of Disease Burden	Introduction to Research Project Management	-HCV-HBV-HEV Infections -Integrated Treatment Strategies -HPV Infections
10:00 - 11:00	Study Designs: Ecological; Cross- Sectional	Time Management and its Impact on Timely Deliverables	-Epidemiology and Treatment of Cervical Cancer -Combined Treatment of Head and Neck Tumors -Discussion
11:00 - 11:30	Tea/Coffee Break		reak
11:30 - 12:00	Study Designs: Case-		Burkitt Lymphoma: Epidemiology and Treatment Masalu N, McGrath I
12:00 - 12:30	Control; Cohort, Experimental	**See below for site visit information.	The Bugando Medical Center Experience (Faustine L. (BMC)/Masalu N-lucas will be in Uganda)
12:20 - 12:40			The EMBLEM Study Kinyera T
12:40 - 13:00			Discussion
13:00 - 15:00		Lunch	
15:00- 16:00	Chance, Bias, and Confounding	Human Resource Management: Acquiring, Developing and Managing the Team	-The Eradication of Helicobacter Pylori -Biology and Medical Treatment of Gastric Cancer -Schistosomiasis: Sources,
16:00 - 16:30	Tea/Coffee Break		Treatment and Prevention
16:30-17:30	Matching and Interaction	Cost Management	
17:30-18:30	Screening, Measurement, Validity and Reliability	Quality Management	-Local and Systemic Treatment of Bladder Carcinoma -Discussion

^{**11:30 -15:00 -} EMBLEM Study Monitoring Visit at Bugando Medical Center (Moses Joloba, Samuel Kirimunda and Bugando staff to be determined)

Wednesday, September 19, 2012

9:00 - 10:00	Role of Cancer Registration in Measurement of Cancer Burden	Scenarios from the Field: Management Strategies that Work	-"HIV Related Tumors" -HIV Infections Control
10:00 - 11:00	Sampling Methods: Probability and Non- Probability Samples	Research Project Management: Writing an Effective SOW	-Kaposi's Sarcoma
			-Epidemiology and Clinical- Pathologic Characteristics of AIDS-Related Lymphomas
11:00 - 11:30	Tea/Coffee Break		
11:30-12:30	Introduction to Statistics in Epidemiology: Descriptive, Hypothesis Testing and Making Inferences	Risk Management	-The Vittorio Tison Association -AFRICONG (African-Italian Cooperative Oncology Group
12:30-13:30	Measurement of Association: Odds Ratios, Relative Risk and Attributable Fraction	The Project Management Plan	RetinoblasomaBreast Cancer Biology Concluding Remarks
13:30-15:30	Lunch		
15:30 - 17:30	Ethics and the EMBLEM Study Consent Dr. Robert Wachbroit (University of Maryland)		
17:30 - 18:00	Tea/Coffee Break		

Thursday, September 20, 2012

8:00 -9:00	Study Monitoring Overview and Role of the Study Monitor
	Moses Joloba MD, Samuel Kirimunda: Presenters
9:00-10:00	A Review of the EMBLEM Consent Process
	Moses Joloba MD, Samuel Kirimunda: Presenters
10:00 - 11:00	Sample Management and Specimen Query Resolution
	Moses Joloba MD, Samuel Kirimunda: Presenters
11:00 - 11:30	Tea/Coffee Break
11:30 - 12:10	Data Quality Management
11.30 - 12.10	Moses Joloba MD, Samuel Kirimunda: Presenters
	EMBLEM Site-Specific Challenges
12:10 - 12:50	Moses Joloba MD, Samuel Kirimunda: Presenters
	Preventative and Corrective Actions
12:50 - 13:30	Moses Joloba MD, Samuel Kirimunda: Presenters
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13:30 - 15:30	Lunch
15:30-17:30	Wrap-up Session: Workshop Action Items, Certificate Distribution,
	and EMBLEM in 2013
	Dr. Martin Ogwang, Dr. Sam Mbulaiteye, and Distinguished Guests*
17:30 - 18:00	Tea/Coffee Break

*Invited Distinguished Guests:

RMO Valentino Bangi Nyamagana Member of Parliament Hezekia Wenje Medical Superintendent Bunda-Lilian Ikangila Medical Superintendent Rorya-Simon Ogendo Medical Superintendent Bukumbi-Deous Malulu